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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NAFF, DAVID M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/718,729

Applicant(s)

MATSUMOTO, TORU

Examiner

David M. Naff

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-15, 24-27, 30-34, 36, 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-23, 28, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/08 has been entered.

An amendment filed 3/5/08 amended claims 1, 8, 16, 24, 25, 30, and 35-39, and canceled claim 29.

Claims in the application are 1-28 and 30-39.

Claims 8-15, 24-27, 30-34, 36, 38 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/19/06.

Claims examined on the merits are 1-7, 16-23, 28, 35 and 37.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 16-23, 28, 35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Adequate support is not found in the specification for "the adhesion layer is formed only on the immobilized enzyme layer" recited in the last line of the independent claims. This recitation does not occur in the specification. While the amendment refers to sections of the specification for support, clear support is not found in these sections of the specification. It is unclear why these sections of the specification were considered to provide support.

Adequate support is not found in the specification for grooves on the outer surface of the permeation-limiting layer. The specification fails to disclose the permeation-limiting layer having an outer surface, and this surface having grooves.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 16-23, 28, 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Reciting "the adhesion layer is formed only on the immobilized enzyme layer" at the end of independent claims is confusing since the
5 adhesion over the immobilized enzyme layer is required in line 4 of the claims. The adhesion layer being formed only on the immobilized enzyme layer should have been required where the adhesion layer is required, and not later after claiming another layer.

Claim 16 and claims dependent thereon are unclear by not having
10 clear antecedent basis in claim 16 for "the outer surface" (penultimate line).

Claim Rejections - 35 USC § 103

Claims 1-7, 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto (EP 0 969 282 A2) in view of
15 McAffrey et al (5,696,314) and Cozzette et al (5,200,051).

The claims are drawn to an enzyme electrode comprising an electrode on an insulating substrate, an immobilized enzyme layer on the electrode, an adhesion layer comprising a silane-containing compound over the immobilized enzyme layer, and a permeation-limiting
20 layer comprising a fluorine-containing polymer having a pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer formed on the adhesion layer. The adhesion layer is formed only on the immobilized enzyme layer.

Matsumoto discloses an enzyme electrode that is the same as
25 presently claimed except the enzyme electrode of Matsumoto contains a

binding layer (adhesion layer) between an electrode and immobilized enzyme layer instead of between the immobilized enzyme layer and the permeation-limiting layer as claimed. For example, see Figures 1 and 2, and description of the figures (page 13, line 15 to page 14, line 40).

McCaffrey et al disclose a multilayer enzyme electrode (Figure 1) that contains an adhesive layer that promotes adhesion between an immobilized enzyme layer and an enzyme/polymer layer, and between a dielectric layer and a microporous layer (col 7, lines 47-59).

Cozzette et al disclose a biosensor containing multiple layers. Adhesion between layers can be provided using a silane compound mixed with a solvent (col 26, section 5.1.2).

It would have been obvious provide an adhesion layer between the immobilized enzyme layer and the permeation-limiting layer of Matsumoto as suggested by McCaffrey et al using an adhesion layer to promote adhesion between a dielectric layer and a microporous layer, and between an immobilized enzyme layer and a enzyme/polymer layer, and Cozzette et al disclosing providing adhesion between multiple layers of a biosensor and using a reagent that provides adhesion between the layers. Having good adhesion between the immobilized enzyme layer and permeation-limiting layer of Matsumoto would have been expected to be advantageous, and using an adhesion layer would have been obvious in view of McCaffrey et al and Cozzette et al providing adhesion between layers of a multiple layer enzyme electrode and multiple layer biosensor by providing between layers a substance

that promotes adhesion. Having the adhesion layer only on the immobilized enzyme layer would have been a matter of choice depending on individual preference. If one desires good adhesion only between the immobilized enzyme layer and the permeation-limiting layer, it would have been obvious to use the adhesion layer only between these two layers. The conditions of dependent claims would have been obvious from conditions disclosed by Matsumoto, and if needed conditions disclosed by McCaffrey et al and Cozzette et al. Using a solution of silane-containing compound to form the adhesion layer as in claim 35 would have been obvious since water is a readily available solvent.

Response to Arguments

The amendment urges that Matsumoto fails to suggest that adhesion of the permeation-limiting layer to the immobilized enzyme layer is insufficient. However, Matsumoto does not disclose that an adhesion layer will not improve adhesion between the layers. Using an adhesion layer as suggested by McCaffrey et al and Cozzette et al would have been obvious even if there is some adhesion between the permeation-limiting layer and the immobilized enzyme layer since the adhesion layer would have been expected to provide additional adhesion. In McCaffrey et al and Cozzette et al, there is adhesion between layers in the absence of the adhesion layer, but when using the adhesion layer there is stronger adhesion. It is clear from the McCaffrey et al and Cozzette et al that an adhesion layer can be other than between an electrode and immobilized enzyme layer. McCaffrey et al disclose

an adhesion layer between an immobilized enzyme layer and a polymer layer, and Cozzette et al disclose adhesion between multiple layers of a biosensor can be provided using a silane compound mixed with a solvent. Therefore, it would have been obvious that an adhesion layer
5 can be used between any layers where adhesion is not considered sufficient or additional adhesion is desired. It would have been obvious to provide the adhesion layer of Matsumoto also between the enzyme layer and permeation-limiting layer if adhesion is not considered sufficient or more adhesion is needed. The amount of
10 adhesion that is considered enough will depend on individual preference. There is seen nothing adequate to lead one to believe the silane-containing adhesion layer of Matsumoto will not provide adhesion between the permeation-limiting layer and the enzyme layer when additional adhesion between these layers is considered needed.
15 Matsumoto discloses (page 13, paragraph (0123)) that the adhesion layer also provides selective permeation and wettability. Having the adhesion layer also between the enzyme layer and the permeation-limiting layer would have been expected to be beneficial in further controlling substances that contact the enzyme and the electrode.
20 Additionally, the wettability provided would have been expected to result in adhesion with a layer that is more hydrophobic.

In response to arguments concerning the disclosures of McCaffrey et al and Cozzette et al, these references are applied in combination with Matsumoto, and the invention becomes obvious when the references
25 are considered in combination rather than each alone. It would have

been well within the ordinary skill of the art to determine whether adhesion between layers is adequate, and when adhesion is not considered adequate, it would have been obvious to use a known way of improving adhesion, i.e. by using an adhesion layer. No unexpected
5 result has been established to be obtained from using an adhesion layer as claimed.

Claim Rejections - 35 USC § 103

Claims 16-23 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-7, 28 and 35
10 above, and further in view of Schillig et al (6,461,861 B2).

The claims require an enzyme electrode formed on an insulating substrate, an immobilized enzyme layer on the electrode, an adhesion layer on the immobilized enzyme layer and a permeation-limiting layer formed on the adhesion layer, wherein the permeation-limiting layer
15 consists of a film comprising a fluorine-containing polymer having a pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer, and a plurality of grooves of a depth in the range of 0.1-100 nm only on the outer surface of the permeation-limiting layer.

20 Matsumoto, McCaffrey et al and Cozzette et al are described above.

Schillig et al disclose a microbial membrane reactor for use in flow systems. The membrane may be fixed adjacent an electrode (col 1, line 47-48). Flow channels in the form of grooves (col 5, line 17)
25 can be provided for flow of fluid over the surface of the membrane to

provide substances metabolized by microorganisms contained by the membrane (col 2, lines 45-59 and col 3, lines 33-48).

When modifying Matsumoto to have an adhesion layer as set forth above, it would have been obvious to provide the permeation-limiting layer of Matsumoto with grooves as suggested by Schillig et al to provide channels for flow of fluid to the immobilized enzyme layer. Selecting a preferred depth of the grooves would have been within the skill of the art and obvious. In regard to claim 17, Cozzette et al disclose a multilayer biosensor, and suggest providing adhesion between layers by producing a rough topography between layers (col 26, lines 35-45). It would have been obvious to provide a surface of the permeation-limiting layer with roughness as suggested by Cozzette et al provide better adhesion between with another layers. Having the grooves on the outer surface of the permeation-limiting layer would have been obvious since the grooves would have been expected to provide their function on the out surface as well as when on an inner surface. Moreover, if a layer is applied to the outer surface of the permeation-limiting layer, the grooves would have been expected to provide roughness to provide better adhesion. The conditions of dependent claims would have been obvious from conditions disclosed by Matsumoto. Providing grooves

Response to Arguments

The amendment urges that Schillig et al fails to disclose grooves on the outer surface of the permeation-limiting layer as now claimed. However, the grooves suggested Schillig et al would have been expected

to provide their function of fluid flow when the grooves are on the outer surface of the permeation-limiting layer. Additionally, if another layer is applied to the outer surface of the permeation-limiting layer, the grooves would have been expected to provide roughness for better adhesion. No unexpected result has been established by having grooves on the outer surface of the permeation-limiting layer.

Double Patenting

Claims 1-7, 16-23, 28, 35 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,280,587 B1 in view of McCaffrey et al and Cozzette et al and Schillig et al..

It would be obvious to provide an adhesion layer between the immobilized enzyme layer and permeation-limiting layer of the enzyme electrode of the claims of the patent as suggested by McCaffrey et al and Cozzette et al for the type of reasons set forth above when applying these references to suggest an adhesion layer. Schillig et al would have suggested the permeation-limiting layer having grooves on the outer surface for reasons set forth above.

Response to Arguments

The amendment traversed this rejection based on arguments traversing the 103 rejection. However, for reasons set forth above, the arguments are unpersuasive with respect to the 103 rejection.

Double Patenting

Claims 1-7, 16-23, 28, 35 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,464,848 B1 in view of Matsumoto (EP) and McCaffrey et al and Cozzette et al and Schillig et al.

It would have been obvious to provide the biosensor of the patent claims with an immobilized enzyme layer on the electrode between the electrode and protection layer (permeation-limiting layer) as suggested by Matsumoto disclosing an immobilized enzyme layer between an electrode and permeation-limiting layer. It would have been further obvious to provide between the immobilized enzyme layer and permeation-limiting layer an adhesion layer as suggested by McCaffrey et al and Cozzette et al for reasons set forth above when applying these references to suggest an adhesion layer. Schillig et al would have suggested the permeation-limiting layer having grooves for reasons set forth above.

Response to Arguments

The amendment traverses this rejection based on arguments traversing the 103 rejection. However, for reasons set forth above, the arguments are unpersuasive with respect to the 103 rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after
5 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX
10 MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

15 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit
1657

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15 5/27/08